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10/718,195

11/20/2003

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7590 05/12/2009  
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EXAMINER
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NGUYEN, CAMTU TRAN

ART UNIT	PAPER NUMBER
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3772

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,195	<b>Applicant(s)</b> RACENET ET AL.	
	<b>Examiner</b> Camtu T. Nguyen	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-20 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-13 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

This Office Action is responding to applicant's amendment filed on 6/23/2008. Claims 5, 9, 11, 17, and 19 have been amended. Claim 20 is newly added.

Applicant amended claim 5 such that it now recites the sealing member having an hourglass shape defining an open aperture in an initial condition thereof, applicant remarked that the Stablein reference does not teaches such limitation. Such remarks are acknowledged and deemed persuasive, Figure 1b in the Stablein reference illustrates the seal member in its hourglass shape but is closed instead of opened. Therefore, the rejection associated with the Stablein has been withdrawn.

The claims, as amended, have been carefully considered but deemed not allowable in view of the following rejection(s).

### ***Claim Objections***

Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 10 recites the sealing member has an hourglass shape configuration, such limitation is already recited in claim 5, therefore, does not further limiting claim 5.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 9, the specification provides no disclosure support for the resilient material disposed within interstices defined by the fabric such that the resilient material is at least partially with the fabric in an integral manner.

Regarding claim 20, the specification provides no disclosure support for the sealing member is non inflatable.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10, 22, 24-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al (U.S. Patent No. 5,634,937) in view of Stablein (DE 37 37 121 A1).

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Mollenauer et al discloses a trocar stabilizer device (10) for accessing to body tissue, the device (10) comprising a cannula member (22) having a longitudinal passage for purposes of receiving an endoscope (34), a sealing member (20) disposed within the cannula member (22) and having an aperture therethrough, as shown in Figure 5. The sealing member (20) defining an opening in an initial condition thereof for receipt of the endoscope (34) and arranged so that the insertion of the endoscope (34) causes the opening of the sealing member (22) to expand to an expanded condition thereof and resiliently contact the outer surface of the endoscope (34) to form a substantially seal therewith.

The Mollenauer et al device does not disclose the sealing member (20) comprising a fabric material.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2.

Therefore, it would have been obvious to one skilled in the art to modify the material of the Mollenauer et al seal (20) such that it would include a layer of fabric, as taught by Stablein, as such would provide not only flexibility during insertion of the endoscope (34) but also greater resistance, thus, to form a tighter fluidic seal in relation about the endoscope (34).

Regarding claims 5 & 10 reciting the sealing member having an hourglass shape, Figure 8 in the Mollenauer et al reference illustrates the device in hourglass shape configuration.

Regarding claim 7, the Mollenauer et al reference discloses the seal (20) is of elastic biocompatible material (column 6 lines 42-49), of which is resilient.

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Regarding claims 8 & 9, the Stablein reference teaches the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2. One skilled in the art would conclude that the reinforcement would entails the sleeve/sealing member is integral with the fabric by disposing the sleeve/sealing member within the interstices of the fabric.

With regards to claim 30 reciting the fabric disposed on each of opposed surfaces of the resilient seal, it would have been obvious to one having ordinary skill in the art at the time the invention was made situate the fabric on each of opposed surfaces of the resilient seal, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al (U.S. Patent No. 5,634,937)/ Stablein (DE 37 37 121 A1), presented above, and further in view of Hu (U.S. Patent No. 5,463,010).

Mollenauer/Stablein a trocar stabilizer device (10) for accessing to body tissue, the device comprising all of the elements as recited in these claims except for the seal member to

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include a coating of material for reducing friction between the seal member and an instrument inserted through the seal member.

Hu discloses and teaches the hydrocyclosiloxane membrane, a coating material for reducing friction between the seal member and the instrument used through the seal member.

Therefore, it would have been obvious to one of ordinary skill in the art to have a coating material applied onto Mollenauer/Stablein's sealing member, as taught by Hu, as such would not only protect biomedical device but also provide lubrication when the instrument is inserted through seal member.

Claims 5, 12, 13, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stephens et al (U.S. Patent No. 5,350,364) and further in view of Stablein (DE 37 37 121 A1).

Stephens et al discloses a trocar assembly (10) to provide access for surgical instrument during endoscopic surgical procedure comprising all of the element as recited in applicant's claims including the seal (234) is non inflatable (claims 20), the seal (234) is of resilient material such as silicone (column 8 lines 65-67) but the seal (234) does not comprising a fabric material as recited in independent claims 5 and 24.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2.

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Therefore, it would have been obvious to one skilled in the art to modify the material of the Stephens et al seal (234) such that it would be reinforced by fabric, as taught by Stablein, as such would minimize frictional forces while inserting/moving implements inside the trocar device (10).

Regarding claim 12, Figure 1 in the Stephens reference illustrates the housing (16).

Regarding claim 13, Figure 7 in the Stephens reference illustrates the flapper valve (164).

Regarding claim 19, Figure 6 in the Stephens reference illustrates a ring (152) and a dampening element (150).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799.

The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772